

# PATENT COOPERATION TREATY

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From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

WRITTEN OPINION

(PCT Rule 66)

To:  
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Date of Mailing (day/month/year) **06 JUN 2003**

Applicant's or agent's file reference

NB 2020.40

REPLY DUE

within 2 months/days from  
the above date of mailing

International application No.

PCT/US02/14500

International filing date (day/month/year)

09 May 2002 (09.05.2002)

Priority date (day/month/year)

09 May 2001 (09.05.2001)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): C07K 5/06 and US Cl.: 514/19

Applicant

NEWBIOTICS, INC.

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

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3. The applicant is hereby invited to reply to this opinion.

**When?** See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension. See rule 66.2(d).~~

**How?** By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

**Also** For an additional opportunity to submit amendments, see Rule 66.4.  
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.  
For an informal communication with the examiner, see Rule 66.6

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is 09 September 2003 (09.09.2003).

Name and mailing address of the IPEA/US  
Mail Stop PCT, Attn: IPEA/US  
Commissioner for Patents  
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Authorized Officer

David Lukton

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# WRITTEN OPINION

International application No.

PCT/US02/14500

## I. Basis of the opinion

1. With regard to the elements of the international application:\*

☒ the international application as originally filed

☒ the description:

pages 1-48, as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of \_\_\_\_\_

☒ the claims:

pages 49-53, as originally filed

pages NONE, as amended (together with any statement) under Article 19

pages NONE, filed with the demand

pages NONE, filed with the letter of \_\_\_\_\_

☒ the drawings:

pages 1-5, as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of \_\_\_\_\_

☐ the sequence listing part of the description:

pages NONE, as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of \_\_\_\_\_

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

☒ the description, pages NONE

☒ the claims, Nos. NONE

☒ the drawings, sheets/fig NONE

5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."

**WRITTEN OPINION**

International application No.  
PCT/US02/14500

**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. STATEMENT**

Novelty (N)	Claims <u>1-26</u>	<b>YES</b>
	Claims <u>NONE</u>	<b>NO</b>
Inventive Step (IS)	Claims <u>1-26</u>	<b>YES</b>
	Claims <u>NONE</u>	<b>NO</b>
Industrial Applicability (IA)	Claims <u>1-26</u>	<b>YES</b>
	Claims <u>NONE</u>	<b>NO</b>

**2. CITATIONS AND EXPLANATIONS**

Claims 1-26 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the claimed compounds or methods of using them.

Claims 1-26 meet the criteria set out in PCT Article 33(4), and thus industrial applicability because the subject matter claimed can be made or used in industry.

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VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claims 24-25 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6. Claim 24 is drawn to a method for treating a subject, but does not cite an objective of the treating, thereby rendering the claim indefinite. Claim 25 is drawn to a method of identifying potential therapeutic agents, but does not specify what the criteria are for a compound to qualify as a "therapeutic agent".

Claims 24-26 are objected to as lacking clarity under PCT Rule 66.2(a)(v) because the claimed invention is not fully supported by the description. The description does not disclose the claimed invention in a manner sufficiently clear and complete for the claimed invention to be carried out by a person skilled in the art.

In the description, data is presented which shows that the claimed compounds can inhibit growth of bacteria. Claim 24 encompasses treatment of any disease, including those caused by bacteria. Claim 25 encompasses any method of identifying a compound that can be used to treat a disease. All diseases would be encompassed, including those caused by bacteria. While it may be true that the claimed compounds are effective to inhibit growth of bacteria in vitro and in vivo, it does not necessarily follow the compounds will be effective to treat diseases caused by bacteria. The rate of proliferation of the bacteria might be reduced somewhat following administration of a claimed compound to an infected host, but if the population of the bacteria continues to increase, an effective treatment will not have been achieved. An efficacious therapy cannot be predicted on the basis of in vitro data. In addition, claim 24 encompasses treatment of diseases which are not caused by bacteria; similarly, claim 25 encompasses an identification of compounds which would be effective in the treatment of treatment of diseases which are not caused by bacteria. The description does not provide any guidance as to which other diseases can be effectively treated, or why a skilled medical practitioner would expect efficacy in the treatment of treatment of diseases which are not caused by bacteria. Accordingly, the description does not disclose the invention of claims 24-25 in a manner sufficiently clear and complete for the claimed invention to be carried out by a person skilled in the art.

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**Supplemental Box**  
(To be used when the space in any of the preceding boxes is not sufficient)

**TIME LIMIT:**

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.

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